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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,371

09/17/2003

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EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

07/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,371	<b>Applicant(s)</b> ORBAY, JORGE L.	
	<b>Examiner</b> Anu Ramana	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 37,38,40-43,45-55,58-61 and 65-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37,38,40-43,45-55,58-61 and 65-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 19, 2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-38, 40-43, 45-55, 58-61 and 65-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 37, 48, 59 and 65, the limitation, "within the proximal-distal and medial-lateral boundaries defined between respective adjacent peg holes" is not supported by Applicant's disclosure since it includes the undisclosed feature of a hole overlapping a hole.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-38, 40-43, 45-55, 58-61 and 65-69 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 37, 48, 59 and 65, the limitation, "within the proximal-distal and medial-lateral boundaries defined between two adjacent or respective adjacent peg holes" renders the claims vague and indefinite since it is unclear what these boundaries are. The Examiner suggests that the proximal-distal and medial-lateral boundaries be defined with respect to the edges of the peg holes.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

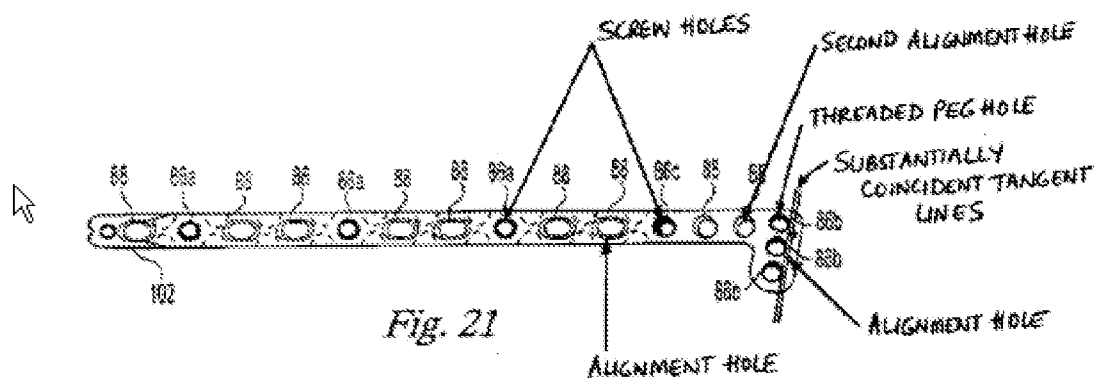
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37-38, 45-48, 51 and 53-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Weaver et al. (US 6,623,486).

Weaver et al. disclose a bone fixation plate 80 including: a head angled relative to a the shaft; the head portion defining a first set of threaded holes 86b; alignment holes much smaller in diameter than the threaded holes for provisional fixation of the bone plate; a second alignment hole 88; and a plurality of screw holes 86a in the shaft of the bone plate (Figs. 20-26, col. 6, lines 58-67 and col. 7, lines 1-17). See marked up Fig. 21 from Weaver et al. on the following page.

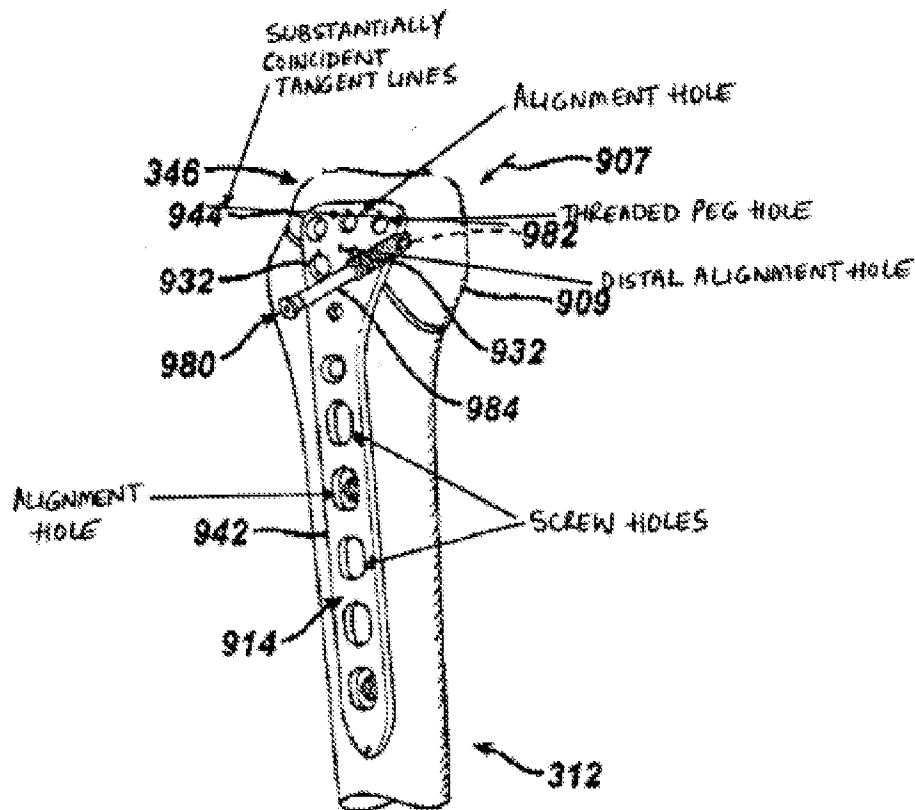
Art Unit: 3733



Claims 37-38, 40-43, 45-46, 48-51, 53-55, 58-59 and 65-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Wack et al. (US 2004/0030339 A1).

Wack et al. disclose a plate 914 defining a first set of peg holes structurally adapted to engage a threaded head of a fixation peg and at least one non-threaded alignment hole 871 having a second relatively small diameter wherein the first alignment hole defines a tangent line substantially coincident with a line tangent to the first set of threaded (Figs. 20-22 and paras [0118]-[0162]). See a portion of Fig. 20 marked up to show features of Applicant's invention below.

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### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wack et al. ((US 2004/0030339 A1) in view of Klaue et al. (US 5,002,544).

Wack et al. disclose all elements of the claimed invention except for the specific shape of the hole.

Klaue et al. teach providing a hole in a bone plate wherein the hole has a wider cross section toward the bone application side of the bone plate in order to permit the insertion and gliding of inclined screws or fixation members (Fig. 5 and col. 2, lines 59-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided holes having a cross section as taught by Klaue et al. in the bone plate of Wack et al. to permit the insertion and gliding of inclined fixation members.

The combination of Wack et al. and Klaue et al. discloses all elements of the claimed invention except for the shape of the hole at the upper surface of the bone plate being circular and the shape of the hole at the bottom surface of the bone plate being oblong. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the hole with the claimed cross sectional shapes at the upper and lower surfaces of the bone plate, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a hole in a bone plate. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wack et al. ((US 2004/0030339 A1).

Wack et al. clearly disclose alignment holes 871 in the head portion of the bone plate (para [0139]).

It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to have provided  $n-1$  alignment holes for  $n$  peg holes, since Applicant has not disclosed that providing a specific number of alignment holes between a specific number of peg holes provides an advantage. One of ordinary skill in the art, furthermore, would have expected the Wack et al. bone plate and applicant's invention, to perform equally well with either  $n+1$  alignment holes for  $n$

peg holes or the claimed “n-1 alignment holes for n peg holes” because both numbers of alignment holes would perform the same function of provisionally fixing the plate to the bone.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver et al. (US 6,623,486) in view of Klaue et al. (US 5,002,544).

Weaver et al. disclose all elements of the claimed invention except for the specific shape of the hole.

Klaue et al. teach providing a hole in a bone plate wherein the hole has a wider cross section toward the bone application side of the bone plate in order to permit the insertion and gliding of inclined screws or fixation members (Fig. 5 and col. 2, lines 59-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided holes having a cross section as taught by Klaue et al. in the bone plate of Weaver et al. to permit the insertion and gliding of inclined fixation members.

The combination of Weaver et al. and Klaue et al. discloses all elements of the claimed invention except for the shape of the hole at the upper surface of the bone plate being circular and the shape of the hole at the bottom surface of the bone plate being oblong. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the hole with the claimed cross sectional shapes at the upper and lower surfaces of the bone plate, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a hole in a bone plate. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver et al. (US 6,623,486) in view of Putnam et al. (US 5,586,985).



Weaver et al. disclose all elements of the claimed invention except for the use of K-wires for provisional fixation of bone plate 80.

Putnam et al. teach the use of K-wires for provisional or temporary fixation of a bone plate to a bone surface (col. 7, lines 63-67 and col. 8, lines 1-14).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized K-wires as taught by Putnam et al. to temporarily fix the Weaver et al. bone plate to bone since it was well known in the art to use K-wires to temporarily or provisionally fix a bone plate to bone.

### ***Response to Arguments***

Applicant's arguments submitted under "REMARKS" in the response filed on March 19, 2007 have been fully considered but are not persuasive for the following reasons.

Applicant's arguments with respect to the rejections of claims 37-38, 45-48, 51 and 53-55 under 35 USC 102(e) as being anticipated by Weaver are not found to be persuasive since the limitation, "entirely within the proximal-distal and medial-lateral boundaries defined between adjacent peg holes" only requires an alignment hole to be in the general vicinity of adjacent peg holes since the claimed "boundaries" are not defined with respect to physical structural features, for e.g., edges of the holes.

Applicant's arguments with respect to the rejections of claims 37, 38, 40-43, 45-46, 48-51, 53-55, 58-59 and 65-69 under 35 USC 102(e) as being anticipated by Wack et al. are not found to be persuasive because the limitation, "entirely within the proximal-distal and medial-lateral boundaries defined between adjacent peg holes" only requires an alignment hole to be in the general vicinity of adjacent peg holes since the claimed "boundaries" are not defined with respect to physical structural features, for e.g., edges of the holes.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
June 28, 2008

/Anu Ramana/  
Primary Examiner, Art Unit 3733